B1 The invention relates to an implantable breast prosthesis adapted more particularly to breast augmentation surgery and breast reconstructive surgery.

2. Discussion of Background Information--

Please replace the two paragraphs between lines 25-33 on page 1 of the specification with the following (see Appendix 2 for changes):

B2 --SUMMARY OF THE INVENTION

The present invention is an improvement to the design of breast prostheses, this improvement aiming particularly at a more aesthetic aspect, which is closer to that of the natural breast, regardless of whether the person wearing the prosthesis is seating, standing, or laying down, and/or a greater ease in positioning the prosthesis correctly during implantation, and/or a more constant retention of the prosthesis once it is implanted in the correct position, and/or a greater comfort in wearing the prosthesis.

According to the invention there is provided a breast prosthesis comprising a soft pouch capable of containing a sufficiently fluid filling material, such as a silicone or hydrocolloid gel or a physiological serum, the prosthesis being made side-specific.--

Please replace the paragraph between lines 25-26 on page 2 of the specification with the following (see Appendix 3 for changes):

B3 --This side-specific arrangement can be obtained at various levels, which can be alternative, or preferably cumulative and which can be seen by referring to the drawings.--

Please replace the paragraph between lines 4-13 on page 3 of the specification with the following (see Appendix 4 for changes):

B4 --Preferably, this asymmetry is defined by a difference in the dimensions between the projection of the distance EC between the nipple and the front inner edge, on the one hand, and the projection of the distance EA between the nipple and the front outer edge, on the other hand, the projections being made along a plane P2 perpendicular to the plane P1 passing by the aforementioned nipple and containing the nipple E as well as the front upper edge B. The ratio between these two projections is advantageously less than or equal to 0.95, especially in the range of between 0.8 and 0.9, or between 0.85 and 0.90. The preferred embodiment utilizes a ratio on the order of 0.875, which is most capable of reproducing the more outwardly projecting aspect of the natural breast, whereas the currently available prostheses have a ratio strictly equal to 1.--

Please replace the paragraphs beginning on line 8 of page 5 and ending on line 17 of page 6 of the specification with the following (see Appendix 5 for changes):

B5 --The invention concerns the protheses having at least one level of side-specific

arrangement and pertaining to the family of prostheses described in the present application. It relates to prostheses having all of the volumes commonly used in breast surgery, namely, prostheses which, once filled, have a volume ranging from 80 cm^3 to 700 cm^3.

The invention also provides for an implantable breast prosthesis which is specific to either a right breast side or a left breast side of a patient, the prosthesis comprising a soft pouch adapted to contain a filling material. The soft pouch comprises a posterior surface, an anterior surface, an inner zone and an outer zone. The posterior surface and the anterior surface form an angle β in the inner zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material. The soft pouch is specific to either the right breast side or the left breast side of the patient.

The filling material may comprise one of a silicone gel and a physiological serum. The soft pouch may be asymmetrical in relation to a plane which passes through an upper zone of the soft pouch, a nipple area of the soft pouch and a lower zone of the soft pouch, when the soft pouch is implanted in the patient and filled. The asymmetry may be defined by a difference in dimensions between a first distance and a second distance defined by a plane passing through the inner zone, the nipple area and the outer zone, whereby the plane passing through the inner zone, the nipple area and the outer zone is perpendicular to a plane passing through the upper zone, the nipple area and the lower zone. The first distance may be different from the second distance. The first distance may be defined between an edge

of the inner zone and a point in the nipple area and the second distance may be defined between an edge of the outer zone and the point in the nipple area. A ratio r of the second distance to the first distance may be less than or equal to 0.95. The ratio r may be in the range of between 0.8 and 0.9. The ratio r may be in the range of between 0.85 and 0.9. The ratio r may be about 0.875. The soft pouch may further comprise a rear outer zone adjacent the outer zone, and wherein the plane passes through the inner zone, the nipple area, the outer zone and the rear outer zone. The prosthesis may further comprise a third distance being defined between an edge of the rear outer zone and a point in the nipple area, whereby the first distance is defined between the point in the nipple area and an edge of the inner zone, the first distance and the third distance being at least one of equal to each other and very close to each other.

The asymmetry may be defined by a difference in dimensions between a fourth distance and a fifth distance defined by a plane passing through the upper zone, the nipple area and the lower zone, whereby the plane passing through the upper zone, the nipple area and the lower zone is perpendicular to a plane passing through the inner zone, the nipple area and the outer zone. The fourth distance may be different from the fifth distance. The fourth distance may be defined between an edge of the upper zone and a point in the nipple area and wherein the fifth distance is defined between an edge of the lower zone and the point in the nipple area. The fourth distance may be greater than the fifth distance. A ratio r of the fourth

distance to the fifth distance may be at least 1.1. The ratio r may be in the range of between 1.1 and 2. The ratio r may be in the range of between 1.3 and 1.5.

The soft pouch further may comprise an outer overlap portion in an area of the outer zone, when the soft pouch is implanted in the patient and filled. The outer overlap portion may extend to each of the upper zone and the lower zone. The outer overlap portion may comprise an anterior surface which forms an obtuse angle ϕ relative to the posterior surface. The angle ϕ may be greater than 95 degrees. The angle ϕ may be greater than 100 degrees. The angle ϕ may be in the range of between 91 degrees and 120 degrees. The angle ϕ may be 115 degrees.

The posterior surface may be at least one of concave and curved. The posterior surface may be at least one of concave and curved between an edge of the inner zone and an edge of the outer zone. The posterior surface may be at least one of concave and curved at least in an area of the inner zone.

A distance between a plane extending through an edge of the inner zone and an edge of the outer zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the inner zone and the edge of the outer zone may be at least 5 mm.

A distance between a plane extending through an edge of the inner zone and an edge of the outer zone and a parallel plane extending through a point on the posterior surface that

is farthest away from the plane extending through the edge of the inner zone and the edge of the outer zone may be at least 1 cm.

The posterior surface may be at least one of concave and curved between an edge of an upper zone and an edge of a lower zone. The surface may be at least one of concave and curved at least in an area of an upper zone.

A distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone may be at least 1 mm.

A distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone may be at least 2 mm.

A distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone may be in the range of between 3 mm and 6 mm.

The anterior surface may be at least one of curved and convex.

A distance between a plane extending through an edge of an upper zone and an edge

of a lower zone and a parallel plane extending through a point on the anterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone may be in the range of between 3 cm and 7 cm.

A distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the anterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone may be on the order of 5 cm.

At least a portion of the posterior surface may be one of less deformable and more rigid than another portion of the soft pouch. The portion of the posterior surface that is one of less deformable and more rigid than another portion of the soft pouch may have a thicker surface than the other portion of the soft pouch.

The posterior surface and the anterior surface may form an angle δ in an upper zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material. The angle δ may be less than 65 degrees. The angle δ may be less than 60 degrees. The angle δ may be about 40 degrees. The angle β may be less than 65 degrees. The angle β may be less than 60 degrees. The angle β may be about 40 degrees.

The soft pouch may comprise an elastomer. The elastomer may comprise silicone. The soft pouch may be adapted to be filled with the filling material either before or after being implanted into the patient. The implantable breast prosthesis may comprise an

expansion prosthesis.

The invention also provides for an implantable breast prosthesis which is specific to either a right breast side or a left breast side of a patient, the prosthesis comprising a soft pouch adapted to contain a filling material. The soft pouch comprises a concave posterior surface, a convex anterior surface, an inner zone, an outer zone, an upper zone and a lower zone. The posterior surface and the anterior surface form an angle β in the inner zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material. The posterior surface and the anterior surface form an angle δ in the upper zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material. The soft pouch is specific to either the right breast side or the left breast side of the patient.

The invention also provides for an implantable breast prosthesis which is specific to either a right breast side or a left breast side of a patient, the prosthesis comprising a soft pouch adapted to contain a filling material. The soft pouch comprises a concave posterior surface, a convex anterior surface, an inner zone, an outer zone, an upper zone and a lower zone. The posterior surface and the anterior surface form an angle β in the inner zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material. The posterior surface and the anterior surface form an angle δ in the upper zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material. A nipple pole zone is defined on each of the posterior surface and the anterior surface. An axis is defined

by a line passing through a point on each of the nipple zones of the posterior surface and the anterior surface, whereby the axis is perpendicular to a plane which extends from an edge of the inner zone to an edge of the outer zone. An upper outer part of the soft pouch is defined by a first plane extending through the upper zone and the lower zone, a second plane extending through the inner zone and the outer zone, an upper outer portion of the posterior surface and an upper outer portion of the anterior surface, whereby each of the first and second planes are perpendicular to each other. An upper inner part of the soft pouch is defined by the first plane, the second plane, an upper inner portion of the posterior surface and an upper inner portion of the anterior surface. A lower outer part of the soft pouch is defined by the first plane, the second plane, a lower outer portion of the posterior surface and a lower outer portion of the anterior surface. A lower inner part of the soft pouch is defined by the first plane, the second plane, a lower inner portion of the posterior surface and a lower inner portion of the anterior surface. Each of the upper outer part, the upper inner part, the lower outer part and the lower inner part have different volumes. The soft pouch is specific to either the right breast side or the left breast side of the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

The details and advantageous characteristics of the invention will now become apparent from the following non-limiting example, by way of Figures 1-6:

Fig. 1 schematically shows a transverse cross-section of a thorax with natural breasts.

Fig. 2 shows the same cross-section with two prostheses according to the prior art.

Fig. 3 shows the same cross-section with two prostheses according to the invention.

B5

Fig. 4 shows a view of the anterior surface along a vertical plane of the right prosthesis according to the invention.

Fig. 5 shows a view of the prosthesis of Figure 4 in a horizontal cross-section.

Fig. 6 shows a side view of the prosthesis of Figure 4.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 is a transverse cross-section of the thorax in a mediastinal window passing by the fourth dorsal vertebra, schematically shown from a scannographic illustration. One sees the spine 10, the two breasts 11 and 12, the mediastinum 13, the lung fields 14 and 15, the costal plane 16. It can be noted that the two breasts "spread" naturally on the thoracic plane 16 by assuming its convex shape. The arrows represent the inner and outer limits of the projection of the two areolar glands on the thorax.

Figure 2 shows, along the same cross-section as in Figure 1, some of the drawbacks of one type of (comparative) prosthesis that is currently commercially available: the prostheses 21 and 22 have planar posterior surfaces 23 and 24 which do not follow the curvature of the thorax. In addition, they create, in the inner zones 25 and 26 for connection with the thorax, an almost 90° angle with the thorax. In almost the same situation in the outer connection zones 27 and 28, the external appearance of the prosthesis is unaesthetic,

on the one hand, and it is susceptible of moving in the pocket where it is implanted, increasing the unaesthetic effect and the discomfort for the person, on the other hand.

B5 Figure 3 shows the prostheses 31, 32 according to a preferred embodiment of the invention. They are much closer to the aspect of the breasts of Figure 1, with a posterior surface 33, 34 assuming the convexity of the thorax as closely as possible, and connections in inner zones 35, 36 and in outer zones 37, 38 along a gentle slope. The prostheses 31, 32 have a volume that is better distributed and closer to the thoracic cage; as a result, they are much less susceptible of moving. It is also seen that the prostheses 31, 32, contrary to the prostheses 21, 22, of the prior art which are not interchangeable, are made side-specific, asymmetrical as are the natural breasts.

The following Figures will discuss the geometry of the prosthesis 31 in detail.

Figure 4 therefore shows a front view of the right prosthesis 31 of Figure 3. It is understood that from this representation, as well as all of the following ones, one can derive those of the left breast 32, which is the mirror construction in volume of the right prosthesis 31. This representation and the following ones are on a scale of 1:1.--

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Please replace the paragraph between lines 24-34 on page 6 of the specification with the following (see Appendix 6 for changes):

B6 --The dimensions of the distances between these various points, measured in the plane

P2, are as follows:

B6

AA' = 1 cm (length of the outer overlap)

A'C = 14 cm (base of the prosthesis)

AC = 15 cm (total width of the prosthesis)

BD = 12 cm (total height of the prosthesis)

DD' = 2 mm

A'E = EC = 7 cm

AE = 8 cm

BE = 7 cm

ED = 5 cm--

Please replace the paragraphs beginning on line 25 of page 7 and ending on line 8 of page 8 of the specification with the following (see Appendix 7 for changes):

B7

--Therefore, one can easily see that the posterior surface 51 has a uniform concavity extending between the points k and C. This concavity can be quantified by the distance GG' which is greater than 1 cm, and by the angles α and α' formed by the planes tangent to the posterior surface 51, at points k and C, with the plane P4. Here, the two angles α and α' on the outer and inner side are substantially identical (about 25°, which can be in the range of between 20° and 30°), but it could also be otherwise. It can be noted that G' is not in the

middle of kC. There is an A'G/G'C ratio of about 0.75 (for example in the range of between 0.5 and 1). The hatched area 53 corresponds to the outer overlap designated by the reference numeral 44 in the previous Figure. This makes it possible to see more clearly that the prosthesis allows obtaining the natural effect of an outwardly projecting breast.

Figure 5 also shows the gentle slope connection mentioned hereinabove, the connection between the inner edge C of the prosthesis and the thorax: thus, the plane P8 tangent to the posterior surface 51 at point C forms, together with the plane P7 tangent to the anterior surface at same point C, a small angle β, much less than 90°, here on the order of 40°.

Figure 5 also shows that the outer overlap 53 also translates into an angle ϕ of about 115°, at point k, between the plane P5 passing by k and tangent to the anterior surface 52 and the plane P6 also passing by k and tangent to the posterior surface 51 of the prosthesis.--

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Please replace the two paragraphs between lines 19-27 on page 8 of the specification with the following (see Appendix 8 for changes):

--The posterior surface 51 has a second concavity in the plane of the Figure. This concavity can be quantified by the distance HH' which is greater than 1 mm, and by the angle χ formed by the plane P10 tangent to the posterior surface 51 at point B with the plane P9. (The situation is the same on the other side near point D' with regard to angle χ', the

concavity extending from B up to D'). Here, the angles χ and χ' are each about 7°, and can be in the range of between 4° and 15°, for example.

B8

Figure 6 also makes it possible to see a second gentle slope connection on the upper zone of the prosthesis: at point B, the angle δ formed by the plane P10 explained hereinabove and the plane P11 tangent to the anterior surface 52 to point B is small, i.e., much less than 90° or 60°, and it is selected here to be about 38.5°.--

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Please replace the paragraph between line 31 on page 8 and line 4 of page 9 of the specification with the following (see Appendix 9 for changes):

B9

--In conclusion, this non-limiting example of prosthesis is the one that combines all of the characteristics of the invention for even closer an approximation to the aspect of the natural breast than before. Prostheses of various volumes can result from mere similarity. However, it remains consistent with the invention to provide prostheses that would not cumulate all of the methods for side-specific arrangement, (adaptation to the convexity of the thorax by a concave posterior surface and/or at least one "gentle slope connection", and/or an asymmetry in relation to a vertical plane passing by the nipple, and/or an outer "overlap"...).--

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